AMENDMENT OF NIAID SOLICITATION
RFP-NIH-NIAID-DAIDS-05-06

"HIV Clinical Research Management Support"

Amendment Number: Two

Amendment Issue Date: August 10, 2004

Proposal Due Date/Time: September 17, 2004, 3:00P.M., EST

Issued By:
Elizabeth J. Shanahan
Contracting Officer
RRCB/CMP/DEA/NIAID/NIH/DHHS
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

Points of Contact:
Elizabeth Shanahan
Contracting Officer
Phone: 301-594-6309
Fax: 301-402-0972
E-Mail: EShanahan@niaid.nih.gov

The hour and date specified for receipt of proposals HAS NOT been extended. Offerors must acknowledge receipt of this amendment by noting, on the face page of the original technical and business proposals, that the proposal has been prepared in accordance with the original solicitation and all of its Amendments. Failure of the offeror to submit this acknowledgment may result in the rejection of their proposal.

PURPOSE OF AMENDMENT: Is to amend the solicitation. Accordingly, the following revisions are incorporated.

The minutes of the Preproposal Conference held on July 26, 2004 for this acquisition are posted and available at the following link:

http://www.niaid.nih.gov/contract/archive/RFP0506_minutes.pdf

The TABLE OF CONTENTS is revised to add Appendices F, G, and H as follows:

APPENDIX F – DAIDS ENTERPRISE SYSTEM (DAIDS-ES) INTERFACE GUIDANCE
APPENDIX G – DAIDS ES STANDARDS
APPENDIX H –CONSOLIDATED HEALTH INFORMATICS INITIATIVE STANDARDS

SECTION J - LIST OF ATTACHMENTS, PROPOSAL SUBMISSION INSTRUCTIONS, Page 41, Table entitled "Number of Copies" - Technical Proposal Appendices is revised as follows:

All materials not available electronically (i.e. Nonscannable Figures or Data, and Letters of Collaboration/Intent). Identify your organizations SOPs and Manuals by topic or title. Also, state if the SOPs are currently in use in a particular study and identify the study.

SECTION K – REPRESENTATIONS AND CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Item 27 is revised to add the following as the last paragraph in the item:

> If offeror(s) cannot make an affirmative statement that they are in compliance with Organizational Conflict of Interest (OCIs) terms and conditions of the solicitation, a mitigation plan shall be submitted. All conflicting interests within the organization must be identified and how those interests have been managed, reduced or eliminated to protect the research from bias and how the Organization will otherwise comply with regulations relating to OCI's.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS:

Subparagraph (1)(b)(3) is revised as follows:

> List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment. The technical areas, character, and extent of consultant activity will be indicated (though individuals shall not be specified).

Subparagraph 2.b.(4) is revised to delete subparagraph a) in its entirety.

APPENDICES A and B are revised and replaced in their entirety as indicated in the attached.

Except as provided herein, all other terms and conditions remain unchanged.

_____

ATTACHMENTS TO THIS AMENDMENT #2:

APPENDIX A (Revised per Amend. 2)
APPENDIX B (Revised per Amend. 2)
APPENDIX F (New)
APPENDIX G (New)
APPENDIX H (New)

APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS
FORMAT FOR TECHNICAL PROPOSAL – TABLE OF CONTENTS

THE BELOW TEMPLATE SHALL BE USED AS THE TABLE OF CONTENTS FOR YOUR TECHNICAL PROPOSAL AND ALL INFORMATION IN YOUR TECHNICAL PROPOSAL SHOULD BE PRESENTED IN THE ORDER SPECIFIED BELOW.

YOU ARE REMINDED THAT THE TOTAL PAGE LIMITATION FOR THE ENTIRE TECHNICAL PROPOSAL PACKAGE IS 150 PAGES. PLEASE REFER TO THE FOLLOWING LINK FOR SPECIFIC PROPOSAL PREPARATION INSTRUCTIONS WITH REGARD TO PAGE LIMITATIONS:
http://www.niaid.nih.gov/contract/eproposal.htm#electronic

THESE ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS REFLECT THE REQUIREMENTS OF THE RFP AND ARE MEANT TO PROVIDE A CLEAR UNDERSTANDING OF THE INTENT OF THIS SOLICITATION.

OFFERORS ARE ADVISED TO GIVE CAREFUL CONSIDERATION TO THE STATEMENT OF WORK, ALL REFERENCE MATERIAL PROVIDED AS APPENDICES AND ATTACHMENTS, AND THE TECHNICAL EVALUATION CRITERIA IN THE DEVELOPMENT OF YOUR PROPOSAL.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

1. **MANDATORY QUALIFICATION CRITERIA**

2. **TECHNICAL APPROACH/METHODOLOGY**

   a. **CORE FUNCTIONS**

      1) **Centralized Clinical Research Program Management**

Your proposal should discuss and demonstrate your experience in the provision of support services for a wide variety of clinical trials conducted in both the U.S. and in resource constrained locales in Africa, Southeast Asia, Latin America/Caribbean and Eastern Europe. You should describe your plans to provide overall management of support services for large scale clinical trials programs along with your approach for coordinating this effort and managing this overarching support project. Areas of emphasis should be:

a) Approach to typical Clinical Trial Project Management
b) Listings of current corporate Standard Operating Procedures
c) Staffing, responsibilities, lines of authority for major functional units
d) Organizational Management structure for current SOW
e) Relevant example of how the company has managed detailed clinical research programs in the past.

b. CONTRACT TRANSITION

Discuss your understanding and experience with the typical risk management practices implemented during the transition of a complex biomedical research project. Explain quality assurance measures in place to audit files before a transition to ensure completeness of transition. Given the breadth and complexity of this project, describe your preliminary plans for executing an effective and efficient transition.

c. NON-CORE FUNCTIONS

THIS PORTION OF YOUR PROPOSAL IS LIMITED TO 25 PAGES AND IS INCLUDED IN THE ENTIRE PROPOSAL PAGE LIMITATION OF 150 PAGES.

SPECIAL NOTE TO OFFERORS:

YOU ARE DIRECTED NOT TO PROPOSE SPECIFIC ORGANIZATIONS WITH WHICH YOU PLAN TO SUBCONTRACT. PROPOSALS THAT PROPOSE SPECIFIC SUBCONTRACTORS WILL BE CONSIDERED NON-RESPONSIVE, AND WILL NOT BE EVALUATED.

Demonstrated skills, knowledge, expertise and past experience to manage the appropriate resources in order to fulfill the requirements for non-core functions detailed in SECTION TWO of the Statement of Work. Discussions should focus on:

1. Your methodology for identifying and obtaining the appropriate expertise necessary to fulfill the requirements under the Non-Core Functions. This should include a discussion which demonstrates your understanding of the knowledge, experience and expertise required to carry out the Non-Core Functions.
2. Your plan for responding to multiple requests for non-core requirements within the same window of time and your plan for prioritizing these requests.
3. Listing of past successful subcontract relationships (relevant to this acquisition) in a table format, including project title, dollar value and period of performance.
4. Lessons learned. Describe the problem(s) experienced and resolution.
5. Plans for identifying and mitigating conflicts of interest.

d. SUBCONTRACT ACQUISITION AND MANAGEMENT

Offerors should discuss and demonstrate their understanding and proposed approach to the subcontracting process in accordance with the requirements established by Federal contracting regulations, utilizing the process identified in the Statement of Work. The Technical Proposal should address:

1) Experience and education of contract management staff in the acquisition and management of subcontracts under a Federal contract.
2) Experience and plan for soliciting, negotiating, awarding and administering subcontracts using a broad range of contract vehicles and mechanisms.
3) Plan for establishing technical review panels for the evaluation of subcontractor technical proposals in excess of $500,000.
4) Experience with identification and remediation of subcontractor performance or noncompliance with subcontract terms and conditions.

5) Plan to compete and award subcontracts with priority given to making awards to subcontractors certified as small and/or disadvantaged in accordance with FAR Part 19.
6) Knowledge and experience in establishing and implementing Small Business Subcontracting Plans.

e. PHASE III CASE STUDY

THIS PORTION OF YOUR PROPOSAL IS LIMITED TO 20 PAGES AND IS INCLUDED IN THE ENTIRE PROPOSAL PAGE LIMITATION OF 150 PAGES.

Due to the nature of this contract and the evolving DAIDS clinical research portfolio, number and types of trials are not known at this time. You should provide a full case study with technical approach with regards to supporting the planning and conduct of a Phase III trial. Specifications for use in developing this hypothetical case study are provided in the table that follows.

- Assume that a "general management" team is in place in the United States.
- Assume that the offeror will either provide the services necessary to support the initiation, conduct and close-out of a Phase III trial or may subcontract out any tasks that are not considered core tasks in Centralized Clinical Research Program Management.
- Discuss your proposed utilization of subcontractors for this proposed trial and the subcontract award process that would be utilized in this case study.
- Any assumptions that you make should be discussed.
- Describe any additional tasks that would typically be added during the conduct of a trial that are not included in the table below (and note if they would be conducted internally or through a subcontract). Throughout the genesis of the case study, the offeror should realize that they will be working with scientific teams at DAIDS and with other DAIDS contractors and at least one DAIDS Network.
- No cost estimate is required to be submitted for this case study.

Trial Task Activity	**Trial Metrics**	**Additional Information**
Sites	20 – all international in Sub-Saharan Africa 10 new 10 established	Do not include site payments but include other site management costs (management and evaluation)
Study Monitoring Plan :		
Subjects	4000 total, 200 divided evenly per site(s). 100% accrual in first year.	
CRF total/subject	15 per subject	
Medical monitoring/SAE Reporting	5% SAE expected	Provide safety monitoring
Immediately reportable SAE	3%	
Trial duration	3 years	
Investigator Meetings	3 - 1 per year in Africa	Arrange 3 Meetings total
Protocol team kick-off meeting	US meeting of protocol team	1 meeting total
Protocol team meeting (teleconference)	100 teleconferences over 3 years	100 total
Protocol Generation, review and finalization (scientific input will come from DAIDS)	3 drafts	Include typical review process (medical, regulatory, others)
Informed Consent Generation and finalization		Include translation and back-translation
Biostatistical input/Stat Analysis Plan/report	Include 1 DSMB report preparation, 1 full statistical report	
Study Manual	3 drafts	
IND Annual Report	Annual	

Source Document Guidelines	3 iterations	
Randomization schedule		Include methodology to randomize
CRF design and printing	Include data management and medical review	
Project training	4 regional trainings for 3 days (Africa)	
Regulatory Documentation Collection Site Registration/Call Center	20 sites	To be located in Africa or Europe
Qualification visits	3 days duration at 10 sites	Describe typical visit
Initiation visits	3 days duration at 20 sites	Describe typical visit
Interim Monitoring	4 days per visit to 20 sites	Describe typical visit
Monitoring frequency	Every 12 weeks, two monitors	
Site specific training (new sites)	10 visits for 7 day periods	Describe training
GCP training	2 regional 3 day trainings	Describe past experience
Site Evaluation visit	1 visit per year per site (operational personnel)	
Site remedial visit	4 visits per year for 5 days each 4 visits to 4 sites each year	Describe typical visit and estimate 4 visits per year
Review, report and track monitoring reports		Describe process
Complete Data Management Services	Develop screens, checks, validation, programming, review, coding, listings, 5 data queries per subject, database audit, archiving, interim and final analysis	Describe system proposed. This may be furnished by a subconctractor.
Study Project Management	Throughout study	Describe study PM and techniques.
Clinical Study Report	3 iterations	
"Internal" Quality Assurance Audit	Make assumption	Describe the task and how to accomplish this

3. PERSONNEL / STAFFING

a. Key Personnel

Several high-level or Key Personnel will be required for this contract.

Describe the experience and qualifications, as well as the percentage of the total time each will be committed to the project. Identify the composition of the task or work group, its general qualifications and recent experience with similar efforts. As a minimum, this effort will require different staff/areas of expertise at different times over the course of the contract. Please provide documentation to describe:

- Limit CVs to 2-3 pages for Key Personnel.
- Qualifications and experience as supported by academic degree(s) and expertise, specialized training, relevant collaborative work involving clinical research, proven ability to provide the necessary scientific leadership/management in designing, managing and coordinating clinical and research components of this multi-site and multi-disciplinary effort.
- Relevant work in planning and/or supporting clinical research as appropriate to the proposed role in the project.
- Availability for the proposed project.

- Managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources and to successfully manage the Project as demonstrated by the management plan and previous relevant experience.

The offeror(s) are charged with providing a plan capable of identifying the need to add, replace, or remove scientific, management, clinical and technical staff, especially subcontractor(s), depending on progress or changes in scientific direction. Offerors are reminded that they are not to include any subcontractor proposals with the proposal submission.

1) **Program Director /Deputy Program Director** - expertise in research program management to include clinical trials with experience in infectious disease(s) and vaccines in international settings, and experience in managing similar large scale efforts with large, multiple trials. Three years minimum experience, minimum bachelor's degree, master's degree is preferable in health/public administration or related science.

2) **Senior Regulatory Director** – Expertise in regulatory affairs surrounding clinical trials in both the U.S. and international settings, including FDA safety reporting requirements, IND annual updates, FDA formal meetings and experience in non-U.S. marketing submissions. Expertise in Good Clinical Practices and application of Quality Assurance in clinical trials. Documented success in management of regulatory activities for large-scale pharmaceutical programs and/or the Federal Government. Three years minimum experience, minimum bachelor's degree, master's degree is preferable in health/public administration or related science.

3) **Lead Monitor** – expertise in the monitoring and oversight of Phase I, II and III infectious disease and/or vaccine trials. Documented experience in the resourcing and monitoring of multiple large scale trials. Three years minimum experience, minimum bachelor's degree, master's degree is preferable in health/public administration or related science.

4) **Floating Project/Site Managers --** Identify and propose, as key personnel, additional staff in specialized areas such as clinical trials and research studies. These Project Managers must be active participants in this project in the area for which they will be serving on the Management Team. Offeror(s) should document relevant education and training, qualifications, expertise, vision, experience with similar projects/competence, suitable time commitment and ability to perform as a member of the proposed management team.

5) **Senior Physician** – Board Certified in infectious diseases with vaccine experience preferred. Extensive clinical trials experience in international settings including safety monitoring, conduct and scientific/medical guidance into protocol development.

6) **Senior IT Specialist** – Systems engineer with experience in IT infrastructure development and the development of programs to support the many aspects of clinical trials.

7) **Lead Trainer** – Experience in the training of personnel, including non-US personnel, in Good Clinical Practices and other training needs associated with clinical trials. Three years minimum experience, minimum bachelor's degree, master's degree is preferable in health/public administration or related science. Documented success in implementation and conduct of clinical trials training programs.

b. **Other Personnel (Non-Key)**

Offeror(s) should discuss the related experience and the role of other personnel. Provision of curriculum vitae(s) is not required in the technical proposal but may be included in the Business Proposal..

c. **Technical and Administrative Staff**

Documented relevant training, education, expertise, experience, competence and availability of the proposed staff to perform their roles in the proposed effort.

d. **Estimate of Effort / Staff Mix**

Refer to APPENDIX B – Additional Business Proposal Instructions (Uniform Assumptions).

4. ORGANIZATIONAL EXPERIENCE, RESOURCES AND FACILITIES

5. HUMAN SUBJECTS

6. OTHER INFORMATION REQUIRED PER SECTION L.2.b. OF THIS RFP

7. PAST PERFORMANCE

APPENDIX B - ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS
[UNIFORM ASSUMPTIONS]

1. Estimated Total Direct Cost

The estimated direct cost for Year 1 for this solicitation is provided below. This is for information purposes only and is not restrictive. All offerors may utilize this estimate when preparing their business proposal and budgets. Each offeror must add their organization's fee and indirect costs based on their most current negotiated indirect rate agreement. It is estimated that the effort and costs for this proposed contract activity may increase by as much as 50 percent in Years 2 through 5.

Year 1 – Estimated direct cost: $12,784,000 (includes uniform assumptions for Travel and Non-Core Functions, noted below.)

2. Estimate of Effort (Non-Core Functions):

Non-Core Functions are defined as highly specialized support that is required in order to sustain the DAIDS growing and evolving clinical research portfolio, although not considered to be key oversight and management functions of this contract. These Non-Core Functions may either be performed by the Contractor or by subcontractors. The Project Officer (PO) will identify requirements for services that fall within the functions designated as Non-Core during the performance of this contract.

Because we cannot quantity this portion of the overall requirement, all offerors are directed to include in their Business Proposal, the following Uniform Budget Assumptions for Years 1 through 5. These amounts represent an increase of 45 percent for each subsequent year after Year 1, representing the estimated increase in support to be required through the proposed contract.

	Uniform Assumptions Non-Core Functions
Year 1	$ 3,230,000
Year 2	$ 4,683,500
Year 3	$ 6,791,075
Year 4	$ 9,847,059
Year 5	$14,278,235
TOTAL	**$38,829,869**

3. Uniform Assumption (Travel):

All offerors are to include a uniform assumption of $1,400,000 per year for staff and meeting travel. This amount should be inflated in accordance with the offeror's proposed rate of inflation.

4. Estimate of Effort (Core Functions ONLY):

The estimated direct labor categories, estimated hours and FTEs (based on a base year of 1880 hours) are identified below. These estimates are provided to assist the offeror(s) in developing their technical and cost proposals for performing the "Core" functions of the SOW requirements and are in no way restrictive. The below table represents the estimated labor needed in Year 1 of the contract. Additional positions may be added as activities increase and personnel are needed to staff the growth. Offeror(s) proposals should reflect

their estimate of staffing increases in Years 2 through 5, based on their interpretation of the requirements of this project.

CORE FUNCTIONS ONLY					
	YEAR 1			**YEARS 2-5 (Avg.)**	
Labor Category	**Estimated Hours**	**Estimated FTEs**		**Estimated Hours**	**Estimated FTEs**
Professional and Technical Staff					
Program Director	1880	1		1880	1
Deputy Program Director	1880	1		1880	1
Senior Regulatory Director	1880	1		1880	1
Clinical Trial Specialist/Operations	0	0		9400	5
Floating Project/Site Manager	0	0		9400	5
Financial Managers	0	0		5640	3
Lead Monitor	1880	1		1880	1
Regulatory Affairs Specialist	1880	1		18800	1
Contracts Specialist	1880	1		5640	3
Recruitment Specialist	0	0		3760	2
Purchasing and Logistics	1880	1		5640	3
Travel Specialist	1880	1		3760	2
Senior Physician	1880	1		1880	1
Lead Trainer	1880	1		1880	1
Legal Specialist	1880	1		1880	1
Senior IT Specialist	1880	1		1880	1
IT Support	37600	2		3760	2
HR Specialist	1880	1		1880	1
Project Assistants	3760	2		9400	5
Central File Clerks	1880	1		7520	4
Facility (Lab)/GMP expert	1880	1		1880	1
TOTAL Professional/Technical Staff:	**33840**	**18**		**84600**	**45**

DAIDS ENTERPRISE SYSTEM (DAIDS-ES) INTERFACE GUIDANCE

The DAIDS Enterprise System (DAIDS-ES) is a comprehensive system that supports the business functions, management and oversight responsibilities of the Division of AIDS. The current components of the DAIDS-ES include:

DAIDS Training Calendar
The DAIDS Training Calendar is an integrated MS-Outlook application to track DAIDS training events. The DAIDS Training Calendar has been developed in response to a need for an easy-to-use system to track and share information about training activities, including content, schedule, participants, travel requirements, registration policies, costs, etc. The system is anticipated in Q3 2004.

DAIDS Master Contact System
The DAIDS Master Contact System is a centralized system for all address and contact information for stakeholders engaged in clinical research, such as investigators, participating institutions, laboratories, agencies, pharmaceutical sponsors, manufacturers, etc. The system is anticipated in Q1 2005.

DAIDS Expedited Adverse Event Reporting System (DAERS)
The DAERS is a web-based application for expedited reporting of adverse events in DAIDS sponsored clinical trials. DAERS is a 21 CFR Part 11 compliant system for use in therapeutic, vaccine and prevention trials. The system is anticipated in Q3 2005.

DAIDS Protocol Management System
The DAIDS Protocol Management System supports end-to-end clinical trials processes, including: protocol development, registration, conduct, accrual, oversight, site monitoring, tracking and closeout. The system is CDISC and HL7 compliant with full auditing capabilities. The system is anticipated in Q4 2005.

Successful offerors will be required to interface, integrate or adapt their information system(s) to interact with these and future components of the DAIDS-ES as necessary.

To achieve compatibility, DAIDS and its collaborators (contractors, cooperative agreement holders, grantees, etc.) will implement applications or data exchange mechanisms using platform technology standards such as: Web Services, eXtensible Markup Language (XML), XML Schema Definitions (XSD), RDBMS, .NET Framework, UDDI, IIS, Internet Explorer, Service Oriented Architecture (SOA), Design Patterns, Frameworks and Templates as defined by the DAIDS-ES. Collaborators shall adhere to these guidelines and standards on a continual basis.

This requirement will include the need to utilize DAIDS-ES specified software Application Programming Interfaces (APIs) or XML and XSD, where appropriate, in all relevant applications that affect specific types of transactions, Graphical User Interfaces (GUI) and other software-based tasks that interact with or become part of the DAIDS-ES.

Depending upon the architecture and implementation of offerors data management system(s), the following activities may be required to be compatible with the DAIDS-ES:

Build Interface:

Using DAIDS-ES specified data standards, collaborators shall provide access to data in their local system(s). Standards shall either be industry data exchange standards such as those specified by NIH, CDISC, HL7 or adapted versions of these as defined by DAIDS.

System Adaptation:

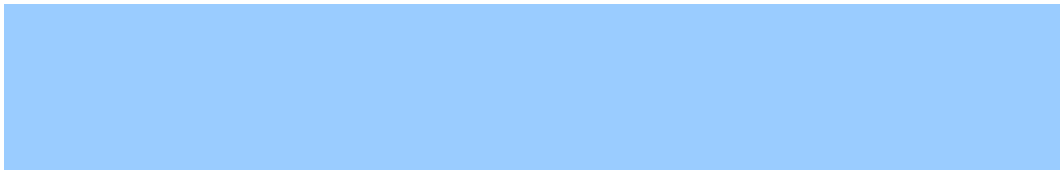
Collaborators may need to adapt or modify their data management system(s) to receive and store data from the DAIDS-ES. For example, DAIDS is establishing a standardized naming and numbering convention for its awardee institutions. The DAIDS shall provide collaborators with a single set of institution or laboratory names and identifiers for all of its research participants. Collaborator's data system(s) may have to be adapted or modified to accommodate the DAIDS standard(s).

System Integration:

Collaborators may be required to dynamically obtain data from the DAIDS-ES to perform specific job functions. This will require the integration of collaborator's system(s) with the DAIDS-ES via data linkages using the appropriate latency factor or through Web Services. For example, the DAIDS-ES will serve as the central repository for investigator and protocol status information. Collaborator's whose work requires information from the DAIDS-ES must dynamically integrate it into their respective data system(s)

.

Clinical Data Management Function	Standard			DAIDS-ES Purpose of the Standard	CHI Standard
	Name	Ver	Authority		
Protocol Development Workflow, Accrual Tracking, Clinical Site Monitoring	ODM	1.2	CDISC	Clinical trials data exchange	Not Defined
	SCTP, COEUS		HL7/CDISC	Protocol authoring and representation	HL7
	HIPAA		HHS	Privacy	HIPAA
	MedDRA	7.0	ICH	AE and Disease Coding	SNOMED CT
Clinical Data Collection	LDM (uses LOINC)	1.0.1	CDISC	Lab data	LOINC
	HL7 - CDA		HL7	Clinical documents	Not Defined
	xODM	1.2	CDISC	Extensions to CDISC ODM for data collection and data sharing	Not Defined
EAE Reporting	SDM	3.1	CDISC	FDA reporting	HL7
	HIPAA		HHS	Privacy	HIPAA
	MedDRA	7.0	ICH	AE Coding	SNOMED CT
DAIDS Master Contact System (People and Organizations)	IPF / D&B		NIH / DEA	Institutional Profile File / Dunn & Badstreet ID for - grantee organization identification	Not Defined
	HIPAA		HHS	Privacy	HIPAA
Underlying software architecture supporting all DAIDS-ES products	ISO/IEC 11179	2nd edition (2003)	ISO	Attribute naming standards	Not Defined
	FEAF		CIO Council	Enterprise architecture development	Not Defined
	RUP		IBM	Software development methodology & tools	Not Defined
	21CFR11		FDA	Electrontic records & signatures	Not Defined
	Section 508		ADA	Usability	Not Defined



Consolidated Health Informatics Initiative Standards

As part of the CHI initiative, HHS and the other federal departments that deliver health care services -- the Departments of Defense and Veterans Affairs -- are working with other federal agencies to identify appropriate, existing data standards and to endorse them for use across the federal health care sector.

The 15 new standards build on the existing set of five standards adopted in March 2003. The new standards agreed to by federal agencies will be used as agencies develop and implement new information technology systems.

"Today we sit at the cusp of creating a 'virtual health system', one that will greatly improve the quality, safety and efficiency of health care for Americans through effective use of electronic health records, personal health records, and standards-based information technology tools," said Veterans Affairs Secretary Anthony J. Principi. "Two years of close collaboration among VA, HHS and DoD have brought about this historic opportunity. The federal government has taken a strong leadership role and
helped lay the critical groundwork for a national public-private health IT partnership."

"Adoption of these standards will increase our ability to share medical data within the health community," said Dr. William Winkenwerder, assistant secretary of defense for health affairs. "Interoperability through standards will enable us to share electronic patient records which will improve the quality of health care. Better access to medical information means improvements in patient safety and military medical readiness, and a
reduction in health care costs."

The CHI initiative is part of President Bush's eGov Initiatives, which
includes a cross-government effort to develop a federal health architecture that would encompass the CHI standards, as well as compatible software and business systems to promote efficient, effective communication to improve quality of care.

"The CHI standards will help improve quality of care by making it easier to coordinate care and exchange needed information across federal agencies and will serve as a model for the private sector," said Karen Evans, administrator for E-Government and Information Technology within the Office of Management and Budget.

The specific new standards are:

- Health Level 7 (HL7) vocabulary standards for demographic
  information, units of measure, immunizations, and clinical encounters, and HL7's Clinical Document Architecture standard for text based reports. (Five standards)
- The College of American Pathologists Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) for laboratory result contents, non-laboratory interventions and procedures, anatomy, diagnosis and problems, and nursing. HHS is making SNOMED-CT available for use in the United States at no charge to users. (Five standards)
- Laboratory Logical Observation Identifier Name Codes (LOINC) to standardize the electronic exchange of laboratory test orders and drug label section headers. (One standard.)

- The Health Insurance Portability and Accountability Act (HIPAA) transactions and code sets for electronic exchange of health related information to perform billing or administrative functions. These are the same standards now required under HIPAA for health plans, health care clearinghouses and those health care providers who engage in certain electronic transactions. (One standard.)
- A set of federal terminologies related to medications, including the Food and Drug Administration's names and codes for ingredients, manufactured dosage forms, drug products and medication packages, the National Library of Medicine's RxNORM for describing clinical drugs, and the Veterans Administration's National Drug File Reference Terminology (NDF-RT) for specific drug classifications. (One standard.)
- The Human Gene Nomenclature (HUGN) for exchanging information regarding the role of genes in biomedical research in the federal health sector. (One standard.)
- The Environmental Protection Agency's Substance Registry System for non- medicinal chemicals of importance to health care. (One standard.)

SNOMED CT Medical Vocabulary

Secretary Thompson also announced that SNOMED CT, a standardized medical vocabulary is now available for download as part of the National Library of Medicine's Unified Medical Language System (UMLS) Metathesaurus at http://umlsinfo.nlm.nih.gov. The vocabulary is available free for anyone in the United States. Users must register via the Web for a free UMLS license before downloading the data or requesting a copy on DVD.

With terms for more than 300,000 current medical concepts, the College's standardized system has been recognized as the world's most comprehensive clinical terminology database available. With its free availability within the United States, it is now possible for health care providers, hospitals, insurance companies, public health departments, medical research facilities and others to easily incorporate this uniform terminology system into their information systems.

More information about HHS' efforts to promote health IT is available at http://www.hhs.gov/news/press/2004pres/20040427a.html